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THORPE NORTH & WESTERN, LLP.
P.O. Box 1219
SANDY, UT 84091-1219

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* MAX R. MOTYKA, RICK HARNISH,
STEPHEN D. ASHMEAD, and H. DEWAYNE ASHMEAD

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Appeal 2009-008329[1]
Application 10/828,827
Technology Center 1600

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Decided: April 7, 2010

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Before JAMES T. MOORE, *Vice Chief Administrative Patent Judge,* RICHARD M. LEBOVITZ, and FRANCISCO C. PRATS, *Administrative Patent Judges.*

PRATS, *Administrative Patent Judge.*

DECISION ON APPEAL

This appeal under 35 U.S.C. § 134 involves claims to methods of preparing and administering hypoallergenic metal amino acid chelate compositions. The Examiner rejected the claims as anticipated and obvious.

We have jurisdiction under 35 U.S.C. § 6(b). We affirm-in-part.

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[1] Albion International, Inc. is the Real Party in Interest (App. Br. 3).

## STATEMENT OF THE CASE

An amino acid chelate can be defined as "the product resulting from the reaction of a metal ion from a soluble metal salt with amino acids having a mole ratio of one mole of metal to one to three (preferably two) moles of amino acids to form coordinate covalent bonds" (Spec. 2). Amino acid chelates are advantageous from a nutritional standpoint because they are "readily absorbed from the gut and into mucosal cells by means of active transport" (*id.* at 4).

However, as "amino acids used to prepare amino acid chelates are typically derived from protein hydrolysis, such amino acids can cause allergic reactions in a small percentage of the population" (*id.* at 5).

Claims 38-54 are pending and on appeal (App. Br. 5). Claims 38 and 46, the independent claims, are representative and read as follows:

> 38. A method of preparing a hypoallergenic metal amino acid chelate composition, comprising:
> a) selecting an amino acid source determined to be hypoallergenic;
> b) selecting a metal source determined to be hypoallergenic; and
> c) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition.

> 46. A method of administering a metal amino acid chelate composition, comprising:
> a) identifying a subject susceptible to a type of allergic reaction;
> b) formulating a metal amino acid chelate by:

i) selecting an amino acid source determined to be hypoallergenic with respect to the type of allergic reaction;

ii) selecting a metal source determined to be hypoallergenic with respect to the type of allergic reaction, and

iii) chelating an amino acid of the amino acid source to a metal of the metal source to form a hypoallergenic metal amino acid chelate composition; and

c) administering the hypoallergenic metal amino acid composition to the subject.

The Examiner cites the following documents as evidence of unpatentability:

| | | |
|---|---|---|
| Hsu | US 5,504,055 | Apr. 2, 1996 |
| Ashmead | US 6,426,424 B1 | Jul. 30, 2002 |
| Ashmead | US 4,725,427[2] | Feb. 16, 1988 |

Yoshiharu Izumi et al., *Production and Utilization of Amino Acids*, 17 ANGEW. CHEM. INT. ED. ENGL. 176-183 (1978).

The Examiner has rejected the claims as follows:

(1) Claims 38-40, 44-46, 48, 49, and 52-54, under 35 U.S.C. § 102(b) as anticipated by Hsu (Ans. 3-4);

(2) Claims 38-40, 44-46, 48, and 49, under 35 U.S.C. § 102(b) as anticipated by Ashmead '424 (Ans. 4-5);

(3) Claims 38-40, 43-49, and 52-54, under 35 U.S.C. § 102(b) as anticipated by Ashmead '427 (Ans. 5-6);

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[2] The Examiner provided an incorrect patent number for Ashmead '427 on page 3 of the Answer.

(4) Claims 41, 42, 50, and 51, under 35 U.S.C. § 103(a) as obvious over Ashmead '427 and Izumi (Ans. 7-8).

ANTICIPATION

*ISSUE*

The Examiner finds that each of Hsu, Ashmead '424, and Ashmead '427 discloses a process that has all of the steps recited in independent claims 38 and 46 (Ans. 3-6). Appellants contend, among other things, that the Examiner has failed to provide an adequate evidentiary basis for finding that the references inherently teach the claimed steps of selecting an amino acid source determined to be hypoallergenic, and selecting a metal source determined to be hypoallergenic (*see, e.g.,* App. Br. 18-21).

The Examiner responds that the Specification defines the term "hypoallergenic" as a composition that does not evoke an allergic reaction in a particular class of subject, due to the absence in the composition of specific allergens, such as soy, peanuts, tree nuts, crustaceans, fin fish, dairy, wheat, and eggs, etc. (*see* Ans. 9). The Examiner reasons that, since none of the references cited as anticipatory discloses such allergens in their compositions, "the Examiner can only reasonably conclude that the prior art compositions and methods of making and using the compositions are hypoallergenic and read on the instant claims" (*id.* at 10).

Moreover, the Examiner argues, it is "contrary to good manufacturing practice to make products with impurities that could be potentially lethal to the consumers ingesting them without a distinct warning label as having those impurities present and it is contrary to conventional wisdom to administer products with those impurities to individuals with known intolerance issues" (*id.* at 11). Therefore, the Examiner finds

> [O]ne of ordinary skill in the art would "determine" the types of impurities in an ingredient, such as a metal or amino acid, before formulating a composition, such as a metal amino-acid chelate, and make an impurity free product and one of ordinary skill in the art would "determine" a susceptible subject, for example a child with a peanut allergy, and not administer a product to that subject with the allergen in it. This is merely common sense.

(*Id.*)

In view of the positions advanced by Appellants and the Examiner, the issue with respect to the anticipation rejections, therefore, is whether Appellants have shown that the Examiner erred in finding that the cited references disclose forming an amino acid metal chelate where the amino acid is from a hypoallergenic source, and the metal is from a hypoallergenic source, as recited in claims 38 and 46.

*FINDINGS OF FACT ("FF")*

*The Claimed Invention*

1. Claim 38 recites a method of preparing a hypoallergenic metal amino acid chelate composition. Both the amino acid and the metal must be from a "source determined to be hypoallergenic."

Claim 46 recites a method of administering a hypoallergenic metal amino acid chelate composition to a subject identified as being susceptible to a type of allergic reaction. Similar to claim 38, the chelate composition must be prepared using an amino acid and metal obtained from a "source determined to be hypoallergenic" with respect to the subject's allergy.

2. The Specification states:

> The term "hypoallergenic" refers to compositions where care has been taken in formulation and/or production to ensure minimal instance of allergic reactions in a target subject or class of subjects. Hypoallergenic can also refer to a composition that when contacted, e.g., topical, or ingested, e.g., food fortification or nutritional supplement, at customary levels to provide a nutritional, cosmetic, or medicinal effect, the contact or ingestion does not produce an adverse discernable allergic reaction to a target subject or class of subjects.

(Spec. 8.)

3. The Specification states:

> The term "allergen" refers to a substance that causes manifestations of allergy, such as a protein or antigen. The FDA lists eight major allergen sources in the FDA Compliance Policy Guide, CPG 555.250, which includes: soy, peanuts, tree nuts (almonds, walnuts, etc.), crustaceans, fin fish, dairy, wheat, and eggs. Other known allergens that affect a relatively large percentage of the population may include corn, from which maltodextrin is derived, gelatin, whey, chocolate, strawberries, etc.

(*Id.* at 8-9)

4. Regarding allergenic metal sources, the Specification states:

> For example, biological sources of metal may more likely include allergens that certain target subjects may be allergic to. Heme iron from hemoglobin, magnesium from chlorophyll, calcium from lactose, magnesium from magnesium stearate each exemplify metal sources that may be undesireable [sic] for use in certain circumstances. However, if such metal sources are processed such that allergens present are reduced to a level that is acceptable, or the use of the metal source would not be problematic with respect to a target subject class, then these metal sources may be acceptable for use. In other words, on a case by case basis, a metal source can be selected for use to

> meet the goals of the hypoallergenic composition to be formed. Examples of metal sources that typically do not include allergens include metal sulfates, metal carbonates, metal oxides, metal hydroxides, elemental metals, and the like.

(*Id.* at 11.)

5. The Specification discloses that "[e]xamples of amino acid sources that can be hypoallergenic include those not prepared by protein hydrolysis, those wherein the amino acid source is prepared by protein hydrolysis using a hypoallergenic protein, and amino acids that have been purified of allergens, such as by chromatography or bind-release separation technologies" (*id.*). Thus, "the naturally occurring amino acid used to make the metal amino acid chelates may be provided by a production method other than protein hydrolysis, e.g., synthetic preparation or fermentation" (*id.* at 12).

*The Prior Art*

*Hsu*

6. Hsu discloses metal amino acid chelates "capable of delivering high levels of desirable metal ions to plants, animals or human beings" (Hsu, col. 1, ll. 44-46).

7. Hsu discloses:

> Highly critical to the invention is the deaeration of the water used to produce the chelate. The presence of dissolved oxygen appears detrimental to the end product as it can result in a shifting of the valence state of the metal (e.g., Fe+2 to Fe+3).
>
> It is also important that the calcium and magnesium content of the water be reduced or eliminated. Suitable procedures include distillation, deionization or softening the water.

(*Id.* at col. 3, ll. 14-22.)

8. Hsu discloses that its process can be applied to "a broad range of metal ions including water soluble salts of iron, cobalt, copper, zinc, manganese, magnesium, calcium, boron, molybdenum, and nickel or mixtures thereof. A list of representative metal salts includes the water soluble carbonates, sulfates, nitrates, oxides, hydroxides, chlorides, phosphates and acetates or mixtures thereof" (*id.* at col. 2, ll. 47-53).

9. Hsu discloses that "[p]referred amino acids include glycine, lysine, methionine, cysteine, glutamic acid and aspartic acid and mixtures thereof" (*id.* at col. 2, l. 67, through col. 3, l. 2).

10. Hsu's examples disclose the preparation of iron/citrate/glycine chelates, calcium/malonic/lysine chelates, and other similar chelates, as well as the administration of a number of those chelates to tomato, corn and bean plants (*id.* at cols. 7-10).

11. Hsu does not disclose that the amino acids used in its processes should be obtained from any particular source, nor does it disclose where the amino acids used in its experiments were obtained.

*Ashmead '424*

12. Ashmead '424 discloses methods of preparing amino acid chelates that "are more granular, dense, and free flowing than other amino acid chelates prepared under similar reaction conditions" (Ashmead '424, col. 4, ll. 33-35).

13. Ashmead '424 states that chelates made by its methods can be used to supply metal nutrients to plants, and also "used in food applications for warm-blooded animals, including humans" (*id.* at col. 7, ll. 62-63).

14. Ashmead '424's chelates are prepared by blending amino acids and hydrated metal sulfates in particulate form with reaction modifiers, and then heating the blend in an enclosed environment "for a time sufficient that the waters of hydration from the hydrated metal sulfate salt are released and provide the moisture necessary to effect a bonding reaction between the electron rich functional groups of the amino acid ligand with the metal ion of the sulfate salt" (*id.* at col. 4, ll. 28-32).

15. Ashmead discloses that the reaction modifiers in the compositions "enhance the physical properties of the compositions and methods of the present invention include any combination of starches, partially hydrolyzed starches, powdered cellulose, and/or modified cellulose. These modifiers may be provided from any know[n] source or in any known form" (*id.* at col. 5, l. 66, through col. 7, l. 4).

16. Regarding the amino acids useful in its methods, Ashmead '424 discloses:

> Since the ligands of the present invention are generally amino acids, the naturally occurring amino acids including alanine, arginine, asparagine, aspartic acid, cysteine, cystine, glutamine, glutamic acid, glycine, histidine, hydroxyproline, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, serine, threonine, tryptophan, tyrosine, valine, and combinations thereof are preferred. However, ligands including dipeptides, tripeptides, and tetrapeptides formed by any combination of the aforementioned amino acids may be used.

(*Id.* at col. 7, ll. 14-23.)

17. In its examples, Ashmead '424 discloses the preparation of chelates using glycine, lysine, and methionine (*id.* at cols. 8-10).

18. Ashmead '424 does not, however, disclose that the amino acids used in its processes should be obtained from any particular source, nor does it disclose where the amino acids used in its experiments were obtained.

*Ashmead '427*

19. Ashmead '427 discloses "[f]lavored, effervescent, water soluble compositions containing water-soluble and oil-soluble vitamins and amino acid chelated minerals in bioavailable form" (Ashmead '427, abstract).

20. Ashmead '427 discloses that it is "well documented that minerals are more bioavailable if administered in the form of chelates wherein the chelating ligands are amino acids or protein hydrolysates" (*id.* at col. 1, ll. 58-61).

21. Ashmead '427 discloses:

> The minerals capable of forming amino acid chelates for which a U.S. RDA has been established are calcium, iron, magnesium, zinc and copper. Manganese is also considered essential although no U.S. RDA has been established. In addition, other chelatable minerals such as cobalt, vanadium, molybdenum, tin, nickel, selenium and chromium are also considered to play essential roles in life's processes. Any or all of these metals, as amino acid chelates, may be utilized in the present invention.

(*Id.* at col. 4, ll. 37-45.)

22. Ashmead '427 discloses:

> Depending upon the ligand used the molecular weight of any amino acid chelate may vary greatly. For example, the

> weight ratio of metal to ligand will be greatest if using pure glycine, the simplist [sic] amino acid, as the ligand. However, if using a polypeptide at the chelating ligand the ratio of metal to ligand will be greatly diminished. Therefore, the amount of amino acid chelate to be blended with the vitamin premix will vary greatly depending upon the number of metals utilized and the metal concentration.

(*Id.* at col. 5, l. 64 through col. 6, l. 5.)

23. In its examples, Ashmead '427 discloses the preparation of a powdered mixes that contain "a mixture of iron, zinc, magnesium, calcium and manganese amino acid chelates and potassium amino acid complex" (*id.* at col. 9, ll. 45-47).

24. Ashmead '427 does not, however, disclose that the amino acids or the metals used in its processes should be obtained from any particular source, nor does it disclose where the amino acids or the metals used in its experiments were obtained.

*PRINCIPLES OF LAW*

As stated in *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992):

> [T]he examiner bears the initial burden . . . of presenting a *prima facie* case of unpatentability. . . . After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument.

"[W]hen the PTO shows sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990); *see also In re Best*, 562 F.2d 1252, 1255 (CCPA 1977).

However, the "very essence of inherency is that one of ordinary skill in the art would recognize that a reference *unavoidably* teaches the property in question." *Agilent Technologies, Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1383 (Fed. Cir. 2009) (emphasis added); *see also In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.").

Thus, if "the disclosure is sufficient to show that the natural result flowing from the operation as taught would result in the performance of the questioned function, it seems to be well settled that the disclosure should be regarded as sufficient." *Oelrich*, 666 F. 2d at 581 (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 214 (CCPA 1939)).

*ANALYSIS*

A preponderance of the evidence supports Appellants' contentions that the Examiner erred in finding that Hsu, Ashmead '424, and Ashmead '427 meet the limitations in the claims requiring the amino acid and metal in the claimed methods to be obtained from hypoallergenic sources.

While Hsu is fairly particular about the oxygen, calcium, and magnesium content in the water used to prepare its chelates (FF 7), Hsu's generic disclosure does not place any specific requirements on the source of its amino acids (*see* FF 9), or identify any suitable amino acid sources, much less a source known or determined to be hypoallergenic as recited in the claims. Hsu does not identify the source of the amino acids used in its examples (FF 10, 11).

We agree with the Examiner that Hsu does not disclose that of any of the allergens identified by Appellants' Specification (FF 3) are present in its compositions. We do not agree, however, that the absence of such a disclosure is a sufficiently sound basis for finding that Hsu's compositions necessarily lack such allergens.

Rather, given Hsu's lack of any positive disclosure that its amino acids should be highly purified or prepared in a particular way, the preponderance of the evidence shows that the natural result of following Hsu's teachings is that Hsu' compositions do not necessarily, that is, do not inherently, contain an amino acid derived from a hypoallergenic source, as that term is defined in the instant application.

We therefore reverse the Examiner's rejection of claims 38 and 46, and their dependent claims, as anticipated by Hsu.

As the Examiner points out, Ashmead '424 similarly fails to disclose that any of its compositions contain the allergens listed in Appellants' Specification. On the other hand, however, Ashmead '424 does not disclose the source of the amino acids used in its examples (*see* FF 17, 18). To the contrary, Ashmead '424's generic disclosure does not restrict the amino acids to any specific sources. It might be true, as the Examiner argues, that a manufacturer producing Ashmead '424's chelates with allergenic starting materials would label them so as to warn the relevant segments of the population of the allergic danger.

However, the Examiner did not provide evidence that such practices, or similar manufacturing standards, demonstrate that producing Ashmead '424's chelates according to that reference's disclosure necessarily entails the use of a hypoallergenic amino acid source, as required by claims 38 and

46, particularly given Ashmead '424's lack of any specific source requirements for its amino acids. We therefore also reverse the Examiner's rejection of claims 38 and 46, and their dependent claims, as being anticipated by Ashmead '424.

Ashmead '427, on the other hand, contemplates using "pure glycine" in its chelates (FF 22). As Appellants' Specification concedes, purified amino acids can be considered hypoallergenic (FF 5).

We acknowledge, as the Examiner argues, that Ashmead '427 does not disclose that its metals were derived from allergenic sources like the ones identified Appellants' Specification (*see* FF 4). Nonetheless, Ashmead '427 does not disclose any specific source for the metals used in its chelates (*see* FF 21, 23). Thus, at best, it is possible that Ashmead '427's metals were obtained from a hypoallergenic source. As noted above, however, inherency cannot be based on probabilities or possibilities.

As the Examiner has not advanced an adequate basis for finding that the metal nutrients used in Ashmead '427's were derived from a hypoallergenic source, we reverse the Examiner's rejection of claims 38 and 46, and their dependent claims, as anticipated by Ashmead '427.

## OBVIOUSNESS

*ISSUE*

The Examiner rejected claims 41, 42, 50, and 51, under 35 U.S.C. § 103(a) as obvious over Ashmead '427 and Izumi (Ans. 7-8). Those claims read as follows:

> 41. A method as in claim 38, wherein the amino acid source is not prepared by protein hydrolysis.

> 42. A method as in claim 38, wherein the amino acid source is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is hypoallergenic.
>
> 50. A method as in claim 46, wherein the amino acid source is prepared by a method other than protein hydrolysis.
>
> 51. A method as in claim 46, wherein the amino acid source is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is hypoallergenic.

The Examiner concedes that Ashmead '427's methods do not prepare amino acids by the methods recited in these claims, and cites Izumi to demonstrate the obviousness of those methods (Ans. 7).

Appellants contend that the Examiner has "failed to show that each and every element of the claimed invention is contained in the combined references" (App. Br. 30). Specifically, Appellants argue, Izumi "never discloses or teaches protein hydrolysis where the protein is hypoallergenic" (*id.* at 31). Additionally, Appellants urge, "even though Izumi discloses various techniques for producing amino acids, Izumi does not teach or disclose each and every element of claims 38 and 46, from which claims 41-42 and 50-51 respectively depend" (*id.*).

In particular, Appellants argue:

> For claim 38, neither Ashmead '427 nor Izumi teach selecting an amino acid determined to be hypoallergenic or selecting a metal source determined to be hypoallergenic.
>
> For claim 46, neither Ashmead '427 nor Izumi teach identifying a subject susceptible to a type of allergic reaction; formulating a metal amino acid chelate by selecting an amino acid determined to be hypoallergenic and selecting a metal source determined to be hypoallergenic; or administering the hypoallergenic metal amino acid chelate composition to a subject.

(*Id.* at 31-32.)

The Examiner disagrees "for the same common sense reasons described in detail above" (Ans. 12). For convenience, we again reproduce the Examiner's summation of his position:

> [O]ne of ordinary skill in the art would "determine" the types of impurities in an ingredient, such as a metal or amino acid, before formulating a composition, such as a metal amino-acid chelate, and make an impurity free product and one of ordinary skill in the art would "determine" a susceptible subject, for example a child with a peanut allergy, and not administer a product to that subject with the allergen in it. This is merely common sense.

(*Id.* at 11.)

In view of the positions advanced by Appellants and the Examiner, the issue with respect to this rejection is whether Appellants have overcome the evidence of record establishing that Ashmead '427 and Izumi would have taught or suggested methods having all of the features recited in claims 41, 42, 50, and 51, to an artisan of ordinary skill.

*FINDINGS OF FACT*

25. Appellants contend, and the Examiner does not dispute, that the company "Similac offers various forms of its baby formula including a regular formula, Similac Advance Infant Formula, and a hypoallergenic formula, Similac Alimentum Hypoallergenic Formula" (App. Br. 25-26 (citing http://welcomeaddition.com)).

26. Izumi discloses that amino acids can be prepared "by extraction from protein hydrolyzates, by fermentation with the aid of microorganisms, by enzymatic processes, and by chemical synthesis" (Izumi 176).

*PRINCIPLES OF LAW*

In *KSR Int' l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007), the Supreme Court emphasized "an expansive and flexible approach" to the obviousness question. The Court nonetheless reaffirmed that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 418.

Rather, as the Court stated:

> [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements *in the way the claimed new invention does* . . . because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

*Id.* at 418-419 (emphasis added); *see also id.* at 418 (requiring a determination of "whether there was an apparent reason to combine the known elements *in the fashion claimed* by the patent at issue") (emphasis added).

The Court advised, however, that in determining whether the prior art supplied a reason for practicing the claimed subject matter, the analysis "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 418; *see also id.* at 421 ("A person of ordinary skill is . . . a person of ordinary creativity, not an automaton.").

*ANALYSIS*

Appellants' arguments do not overcome the evidence of record that Ashmead '427 and Izumi would have suggested methods having all of the features recited in claims 41, 42, 50, and 51, to an artisan of ordinary skill. It may be true, as Appellants argue, that neither Ashmead '427 nor Izumi explicitly states that metal amino acid chelates should be prepared using amino acids and metals from sources determined to be hypoallergenic.

As noted above, however, the obviousness analysis is not limited to the references' explicit disclosures. *KSR,* 550 U.S. at 418. Rather, the analysis must take account of what an ordinary artisan would have inferred from those teachings. *Id.*

Thus, in the instant case, an artisan of ordinary skill preparing a hypoallergenic nutritional product like Similac's baby formula (FF 25) would have been advised by Ashmead '427 of the superior bioavailability of metallic mineral nutrients in chelate form (FF 20, 21). We agree with the Examiner that the ordinary artisan, being a person of common sense, and being prompted by Ashmead '427 to include chelated minerals in such hypoallergenic nutritional formulations, would have been further prompted to prepare the chelates using amino acids and metals from sources determined to be hypoallergenic, as recited in claim 38, so as to avoid a harmful reaction when administering the chelates to allergic individuals, as recited in claim 46.

For similar reasons, we also agree with the Examiner that an ordinary artisan, advised by Izumi that amino acids were obtainable from sources other than protein hydrolysis, such as fermentation or enzymatic or chemical syntheses (FF 26), would have considered it obvious to use those known

amino acid sources in preparing metal amino acid chelates for use in a hypoallergenic product, as recited in claims 41 and 50. With respect to claims 42 and 51, we further agree with the Examiner that, given the concern for an allergic reaction, an ordinary artisan preparing amino acids via protein hydrolysis as disclosed by Izumi (FF 26), for use in hypoallergenic nutritional products, would have been prompted to ensure that the protein starting material was itself hypoallergenic.

Thus, Appellants' arguments do not overcome the evidence of record supporting the conclusion that an ordinary artisan would have considered it obvious to prepare metal amino acid chelates using metals and amino acids obtained from hypoallergenic sources, including known non-protein-hydrolysate sources, or from hydrolysates obtained from hypoallergenic proteins. We therefore affirm the Examiner's rejection of claims 41, 42, 50, and 51 as being obvious in view of Ashmead '427 and Izumi.

## SUMMARY

We reverse the Examiner's rejection of claims 38-40, 44-46, 48, 49, and 52-54, under 35 U.S.C. § 102(b) as anticipated by Hsu.

We also reverse the Examiner's rejection of claims 38-40, 44-46, 48, and 49, under 35 U.S.C. § 102(b) as anticipated by Ashmead '424.

We also reverse the Examiner's rejection of claims 38-40, 43-49, and 52-54, under 35 U.S.C. § 102(b) as anticipated by Ashmead '427.

However, we affirm the Examiner's rejection of claims 41, 42, 50, and 51, under 35 U.S.C. § 103(a) as being obvious over Ashmead '427 and Izumi.

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED-IN-PART

lp

THORPE NORTH & WESTERN, LLP.
P.O. BOX 1219
SANDY, UT 84091-1219